



## UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents  
United States Patent and Trademark Office  
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Ruby T. Hope  
Johnson & Johnson  
One Johnson & Johnson Plaza  
New Brunswick, NJ 08933

In Re: Patent Term Extension  
Application for  
U.S. Patent No. 5,468,743

*MULC*  
OCT 4 2012  
*by DPLA*

Dear Ms. Hope:

An order granting interim extension under 35 U.S.C. § 156(e)(2) is enclosed extending the term of U.S. Patent No. 5,468,743 for a period of 1 year from the original expiration date. While a courtesy copy of this letter is being forwarded to the Food and Drug Administration (FDA), you should directly correspond with the FDA regarding any required changes to the patent expiration dates set forth in the Patent and Exclusivity Data Appendix of the Orange Book (Approved Drug Products with Therapeutic Equivalence Evaluations) or in the Patent Information set forth in the Green Book (FDA Approved Animal Drug Products). Effective August 18, 2003, patent submissions for publication in the Orange Book and Docket \*95S-0117 need to be submitted on form FDA-3542 which may be downloaded from FDA's Electronic Forms Download Website: <http://www.fda.gov/opacom/morechoices/fdaforms/default.html> (<http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3542.pdf>).

Inquiries regarding this communication should be directed to the undersigned by telephone at (571) 272-7755, or by e-mail at [mary.till@uspto.gov](mailto:mary.till@uspto.gov).

  
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Mary C. Till

Mary C. Till  
Senior Legal Advisor  
Office of Patent Legal Administration  
Office of the Associate Commissioner  
for Patent Examination Policy

cc: Office of Regulatory Policy  
Food and Drug Administration  
10903 New Hampshire Ave., Bldg. 51, Rm. 6222  
Silver Spring, MD 20993-0002

RE: LASTACAFT™  
(alcaftadine ophthalmic  
solution)  
Docket No.: FDA-2011-E

Attention: Beverly Friedman

UNITED STATES PATENT AND TRADEMARK OFFICE

In re Janssen Pharmaceutica N.V. :  
Request for Patent Term Extension : ORDER GRANTING  
U.S. Patent No. 5,468,743 : INTERIM EXTENSION

Janssen Pharmaceutica N.V., the owner of record in the United States Patent and Trademark Office (USPTO) of U.S. Patent No. 5,468,743, filed an application for patent term extension under 35 U.S.C. § 156 on September 23, 2010. The original term of the patent is due to expire on November 21, 2012. A request for interim extension was filed on June 12, 2012. The patent claims the active ingredient alcaftadine in the human drug product LASTACAFT™ (alcaftadine ophthalmic solution), which was approved by the Food and Drug Administration for commercial marketing or use on July 28, 2010. An extension of 1,246 days is requested.

The initial USPTO review of the application to date indicates that the subject patent is eligible for extension of the patent term under 35 U.S.C. § 156. A final determination of the length of the extension of the patent term and issuance of a patent term extension certificate cannot be made until a final determination of the length of the regulatory review period is made. Because the original term of the patent would expire before a certificate of patent term extension can be issued, an interim extension of the patent term is appropriate.

An interim extension under 35 U.S.C. § 156(e)(2) of the term of U.S. Patent No. 5,468,743 is granted for a period of one year from the original expiration date of the patent.

September 27, 2012



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Date

David J. Kappos

Under Secretary of Commerce for Intellectual Property and  
Director of the United States Patent and Trademark Office